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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL INC.,

Petitioners,

v.

RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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69 pp

QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts a California statute that requires reproductive toxicity warnings for a medical device, even though the United States Food and Drug Administration has considered and rejected such warnings and imposed different warning requirements on the same device under the FDCA.

RULE 29.6 STATEMENT

Petitioner Dentsply International Inc. has the following nonwholly owned subsidiaries: Stomatologia Dentsply (Stomadent) (Russia); Ceramed, LCC; Industria, e Commercia Ltda. (Brazil).

The Rule 29.6 statement concerning petitioner Committee of Dental Amalgam Alloy Manufacturers and Distributors has been filed under seal.

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COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL INC.,
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RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION,
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On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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PETITION FOR WRIT OF CERTIORARI

Petitioners Committee of Dental Amalgam Manufacturers and Distributors and Dentsply International Inc. ("Committee") hereby petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case. The Ninth Circuit held that a California state statute that requires reproductive toxicity warnings for a medical device is not preempted, even though the United States Food and Drug Administration ("FDA") has considered and rejected such warnings and imposed different warning requirements on the same device under the FDCA. The Ninth Circuit's ruling permits California to require warnings that the United States Department of Health and Human Services has indicated violate federal law.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a) is reported at 92 F.3d 807 (9th Cir. 1996). The opinion of the United States District Court for the Southern District of California granting summary judgment for petitioners (Pet. App. 1c) is reported at 871 F. Supp. 1278 (S.D. Cal. 1994).

JURISDICTION

The court of appeals entered judgment on August 5, 1996. Pet. App. 1a. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The appendix (Pet. App. 1d) sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. 360k and 21 C.F.R. 808.1(d) (excerpt).

STATEMENT OF THE CASE

The Ninth Circuit held that the FDCA's express preemption provision does not bar a California statutory warning requirement for a medical device, even though the FDA has considered and rejected such warnings and imposed different warning requirements under the FDCA. The Ninth Circuit's construction of the FDCA preemption provision conflicts fundamentally with the principles underlying decisions in seven other circuits by concluding that the FDCA does not preempt "general" state laws that apply to medical devices as well as other products. In addition, the decision below conflicts with the premises of decisions in four other circuits by holding that federal requirements do not preempt state law if they regulate more than one type of medical device. This petition asks this Court to review a question of profound significance to all manufacturers and users of medical devices—whether a state legislature may impose requirements

on medical devices that the FDA has considered and rejected as unfounded.

A. Federal Law Background

1. The Statutory Structure

In 1976, Congress passed the Medical Device Amendments ("MDA") to the FDCA, establishing comprehensive federal regulation of medical devices for the first time. Under the MDA, the FDA has extensive authority to ensure the safety and effectiveness of medical devices. Congress enacted the MDA as "a balanced regulatory proposal" intended to assure both that the public health is protected and that "innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). Through the MDA, Congress sought to encourage research and development of "sophisticated, critically important medical devices," as well as to give the FDA the necessary authority to ensure the public health and safety. S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1975).

Consistent with the congressional intent to promote innovation by eliminating unnecessary regulation, the MDA include the following express preemption provision:

> Except as provided in subsection (b) * * * no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a).[1] The House committee report for the MDA describes the preemption provision as a "general prohibition on non-Federal regulation," making clear that Congress intended broad preemption of state law under section 360k. H.R. Rep. No. 853, at 45.

The federal requirements giving rise to preemption under section 360k are extensive. Under the FDCA, the FDA regulates medical devices in the context of a classification scheme that distinguishes among devices based upon the concerns they raise about safety and effectiveness. The FDA assigns medical devices intended for human use to one of three classes, effectuating its classification decision through notice and comment rulemaking procedures. See 21 U.S.C. 360c(b)(1); 21 C.F.R. 860.84. Class I devices, which the FDA believes pose no unreasonable health risks, are subject to general controls designed to ensure that labeling is accurate, that the product is safe when used as directed, and that it has been manufactured under proper quality assurance procedures. See 21 U.S.C. 360c(a)(1)(A). Class II devices are those for which special controls may be necessary to assure safety and effectiveness. *Id.* § 360c(a)(1)(B). These special controls may include performance standards, postmarket surveillance, patient registries, and other requirements the FDA deems appropriate. *Id.* In general, Class III devices are those represented to be life-sustaining or life-supporting, or those presenting a potentially unreasonable risk of illness or injury. *Id.* § 360c(a)(1)(C).

In general, the regulatory structure established by the MDA requires the FDA to review and authorize marketing of new medical devices under one of two clearance processes. First, the FDA authorizes marketing of some Class III de-

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[1] The exception in subsection (b) permits states to apply for an exemption from the preemption imposed by subsection (a). *Id.* § 360k(b).

vices through the premarket approval process. To obtain this authorization, the manufacturer submits a premarket approval application ("PMA") containing significant information about the device for FDA review. If clinical data and other information in the PMA demonstrate that the device's safety and effectiveness are reasonably assured, the FDA approves marketing. See *id.* § 360e(c), (d).

Second, all Class II devices and some devices in Classes I and III are subject to FDA premarket clearance through the "510(k)" process. This process is established by, and named after, section 510(k) of the FDCA, 21 U.S.C. 360(k). Through the 510(k) process, the FDA determines whether devices are substantially equivalent to "preamendment" devices marketed prior to the adoption of the MDA in 1976. The 510(k) substantial equivalence determination is designed to ensure that new devices are as safe and effective as preamendment devices. See H.R. Rep. No. 853, at 36-37 (explaining that substantial equivalence determination involves safety and effectiveness determination).

The MDA define the term "device" broadly, giving the FDA regulatory jurisdiction over a wide spectrum of medical products. Although some devices depend on advanced technology for their operation, others are relatively simple materials that fit the statutory definition of a device because they are implanted into the body and intended for use in the "cure, mitigation, treatment, or prevention of disease, in man or other animals." 21 U.S.C. 321(h)(2). The medical device implicated by the present case is dental mercury—a material used to make silver fillings for the treatment of tooth decay. Dental mercury typically is combined with a second device (amalgam alloy) in the dentist's office to form a third device (dental amalgam) which is used as a filling material for dental cavities. The FDA has assigned dental mercury to Class I and subjected it to premarket clearance through the 510(k) process. Cf. 21 U.S.C. 360c(d)(2)(A); 21 C.F.R. 872.3700.

2. Labeling Requirements

The FDCA establishes five major categories of federal requirements that may govern the labeling of medical devices.[2] First, devices such as dental mercury, which fit the FDA's definition of a prescription device, must comply with the FDA's prescription device labeling regulation.[3] The regulation requires that the labeling must disclose information concerning use of the prescription device and warnings regarding relevant hazards, contraindications and side effects. 21 C.F.R. 801.109(c).

Second, under the FDCA's "general controls" provisions, a device is "misbranded" if the warnings in its labeling are not adequate such that the device may be dangerous to health or if use in accordance with the labeling renders it dangerous to health. 21 U.S.C. 352(f)(2), 352(j). A device also is misbranded if its labeling is "false or misleading." *Id.* §§ 352(a), 321(n).

Third, manufacturers of devices such as dental mercury, which enter the marketplace through the 510(k) process, must submit proposed labeling for agency review to obtain premarket clearance. 21 C.F.R. 807.87(e). After marketing begins, the 510(k) requirements also bar manufacturers from

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[2] The FDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. 321(m). Under the FDCA, "labeling" includes a broad variety of product literature (including technical manuals explaining product use and promotional materials), even if they do not physically accompany distribution of the device. See *Kordel* v. *United States*, 335 U.S. 345, 349 (1948).

[3] A prescription device is one which, "because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device." 21 C.F.R. 801.109.

changing labeling warnings in a manner that could affect safety or effectiveness of the device significantly unless the FDA clears the labeling changes through another 510(k) review. See 21 C.F.R. 807.81(a)(3)(i).

Fourth, the FDA has substantial authority to require additional labeling warnings once marketing begins. Under 21 C.F.R. 895.25, the FDA may require manufacturers to change a device's labeling to contain statements, notices, or warnings if the device presents unreasonable public health risks. 21 C.F.R. 895.25(a), (b).

Finally, under its general rulemaking authority, the FDA may promulgate regulations requiring specific labeling warnings for a particular type of device. See, e.g., 21 U.S.C. 371(a) ("authority to promulgate regulations for the efficient enforcement of [the FDCA]"); 21 C.F.R. 801.420 (hearing aid labeling requirements); *id.* § 801.430 (tampon labeling requirements). The FDA may promulgate such regulations on its own initiative or in response to a petition filed by an interested party. See 21 C.F.R. 10.25 (a), (b). When considering whether to issue such regulations, the FDA typically consults with a panel of outside experts established under the FDCA to advise the Agency about matters requiring particular scientific expertise. See 21 U.S.C. § 360c(b) (authority for establishing expert panels). The Agency has assembled the Dental Device Panel (composed of national experts in the field of dentistry) to perform this function with respect to devices such as dental mercury.

If the FDA considers promulgating a labeling regulation or taking other action to impose significant warning requirements on a particular device but ultimately determines that such requirements are not justified, the FDCA may prohibit the manufacturer from adding the warnings voluntarily. The 510(k) requirements prohibit the addition of labeling warnings that could significantly affect the safety or effectiveness of the device unless the FDA clears them as legitimate. See

21 C.F.R. 807.81(a)(3)(i). This prohibition on changes in labeling applies regardless of whether the manufacturer believes that they would decrease or increase device safety or effectiveness.[4] In addition, if the FDA determines that there is no legitimate scientific basis for the warnings, the general controls provisions of the FDCA barring misleading labeling would prevent the manufacturer from adding the warnings. See 21 U.S.C. 352(a), 321(n).

B. This Litigation

On September 21, 1993, petitioners filed this action for declaratory and injunctive relief in the Southern District of California, Pet. App. 4a, arguing that the FDCA preempts reproductive toxicity warning requirements for dental mercury imposed by California's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code 25249.5-13.[5] Proposition 65 imposes warning requirements on a wide variety of consumer products, including some medical devices regulated by the FDA. With certain exceptions, Proposition 65 prohibits any person from "knowingly and intentionally expos[ing] any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving *clear and reasonable warning* to such individual." *Id.* § 25249.6 (emphasis added). California has designated mercury as a reproductive toxin "known to the state," thereby imposing the statutory warning requirements on dental mercury and other products containing mercury.

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[4] See, e.g., 42 Fed. Reg. 42,520, 42,522 (Aug. 23, 1977) (preamble to 510(k) regulation).

[5] Jurisdiction in the district court was based on the federal question statute, 28 U.S.C. 1331. Pet. App. 2a.

Proposition 65 does not define the terms "clear and reasonable" warning. Instead, it leaves the adequacy of warnings to be determined on a case-by-case basis through lawsuits for civil penalties and injunctive relief under the statute. Proposition 65 vests primary enforcement authority in the Attorney General and district attorneys, but allows private parties (commonly referred to as "bounty hunters") to sue "in the public interest" if the State does not "commence[]" and "diligently prosecut[e]" a suit against an alleged violator within sixty days after receiving notice of the bounty hunter's intent to sue. *Id.* § 25249.7(d).

Proposition 65 gives private parties a significant pecuniary incentive to "enforce" the statute and impose new warning requirements through the litigation process. A bounty hunter who prevails is entitled to one-fourth of any civil penalty imposed, *id.* § 25192, and receives reimbursement of its attorneys fees and costs as long as it achieves a result that is in "the public interest." Cal. Code Civ. Proc. § 1021.5 (West Supp. 1996).

Petitioners, who manufacture and distribute dental mercury in interstate commerce, brought this suit to protect themselves from bounty hunter suits initiated by respondent Environmental Law Foundation ("ELF"). Proceeding under the bounty hunter provision against one small dental mercury distributor, ELF previously had forced a settlement that imposed a series of new warning requirements and significant civil penalties. See p. 22, *infra*. ELF also had issued notices of its intent to sue a number of additional manufacturers, who brought this protective suit in the name of the Committee. In the district court, petitioners argued that federal labeling requirements preempt Proposition 65 warning requirements for dental mercury, emphasizing that the FDA has considered and formally rejected toxicity warnings as unfounded. Petitioners also argued that the Proposition 65

warning requirements for dental mercury violate the Commerce Clause of the U.S. Constitution.

The district court first considered the types of federal requirements that have preemptive effect under the FDCA. The court deferred to the following FDA regulation, which interprets the scope of the FDCA preemption provision (Pet. App. 9c & n.6):

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. 808.1(d). The court concluded that under the regulation, "[a] 'specific requirement' may apply to numerous medical devices and still be preemptive." Pet. App. 12c. The court also held that the regulation "does not state that the [FDCA] preempts state law only when it contains a requirement specifically applicable to one specific device." *Ibid.*

The district court then analyzed the federal requirements applicable to dental mercury. The court held that the prescription device labeling regulation, 21 C.F.R. 801.109, is a specific requirement with preemptive effect. Pet. App. 11c-12c. The court also concluded that there was "no genuine issue of material fact that the FDA has considered, and rejected, imposing reproductive toxicity warning requirements for dental amalgam." Pet. App. 6c.[6] The court held that the

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[6] Dental amalgam is created in the dentist's office from amalgam alloy and dental mercury. See p. 5, *supra*. Both the district court and the Ninth Circuit used the terms "dental mercury" and "dental amalgam" inter-

(Footnote cont'd on next page)

FDA's decision to reject such warnings had preemptive effect.

The district court then turned to the FDA regulation's discussion of the state law requirements that are subject to preemption. According to that regulation, section 360k does not preempt certain state requirements of "general applicability":

> Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices * * * or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. 808.1(d)(1). The district court held that this language does not exclude Proposition 65 from the scope of the FDCA preemption provision. Pet. App. 13c.

The district court then concluded that the Proposition 65 warning requirements are "different from, or in addition to," the applicable federal requirements, *ibid.*, and granted summary judgment for petitioners on the preemption issue, Pet. App. 15c. The district court also denied summary judgment on the Commerce Clause issue because the facts were disputed, *ibid.*, and later concluded that the Commerce Clause claim was moot, Pet. App. 1b.

C. The Court of Appeals Opinion

The Ninth Circuit reversed on the preemption issue. The court premised its ruling on its reading of *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996) (which construed the scope of the FDCA preemption provision in the context of a product

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(Footnote cont'd from previous page.)

changeably, even though the state and federal requirements at issue relate primarily to dental mercury.

liability case), and the FDA's interpretive regulation, 21 C.F.R. 808.1(d). Pet. App. 10a-12a.

The court of appeals held that the Proposition 65 warning requirements are not state "requirements" within the meaning of the FDCA preemption provision. Pet. App. 12a. The Ninth Circuit concluded that in *Lohr*, this Court had "specifically approved" the language of 21 C.F.R. 808.1(d)(1) excluding requirements of "general applicability" from the scope of the preemption provision. Pet. App. 10a. The court of appeals then reasoned that the Proposition 65 warning requirements are requirements of general applicability that are preserved from preemption. Pet. App. 11a-12a.

The Ninth Circuit also held that the federal labeling requirements applicable to dental amalgam are too general to be preemptive under section 360k. The court of appeals again relied on its reading of *Lohr* and of the language in 21 C.F.R. 808.1(d) stating that only "specific" federal requirements have preemptive effect. The court of appeals concluded that to preempt state law, federal requirements must be so specific that they are uniquely applicable to a particular device. Because the federal labeling requirements at issue apply to numerous devices, the Ninth Circuit concluded that Proposition 65 is not preempted. See Pet. App. 9a-11a; pp. 18-21, *infra*.

The court of appeals also held that the FDA's consideration and rejection of reproductive toxicity warnings for dental amalgam was "inaction" by the FDA that does not preempt state law. Pet. App. 12a-13a. In denying preemption, the Ninth Circuit reasoned that the statutory language requires "a positive enactment from the FDA before preemption can be triggered." Pet. App. 12a. The Ninth Circuit's holding therefore preserved state warning requirements from preemption even though the FDA has considered and rejected the same warnings under the FDCA.

REASONS FOR GRANTING THE WRIT

I. THE COURT OF APPEALS DECISION ESTABLISHES PREEMPTION STANDARDS THAT CONFLICT WITH THE STANDARDS IN OTHER CIRCUITS

The Ninth Circuit's decision confirms a substantial conflict in principle among the circuits concerning the scope of federal preemption under the FDCA. The court of appeals decision conflicts with the premises of decisions by seven other circuits regarding the types of state requirements that are subject to preemption. The decision also conflicts with the principles underlying decisions by four other circuits regarding the types of federal requirements that have preemptive effect. In addition, this Court's construction of the FDCA preemption provision last term in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), does not resolve the conflicts.

A. The Conflict Regarding State Requirements Subject to Preemption

One major premise of the Ninth Circuit's holding is that Proposition 65 does not impose a state requirement subject to preemption, because it is "a state law of general applicability which was *not* enacted 'with respect to' medical devices." Pet. App. 11a. The Ninth Circuit concluded that under *Lohr* and the FDA's interpretive regulation (21 C.F.R. 808.1(d)(1)), preemption does not extend to Proposition 65, because it "applies to *all* products and services that pose a health risk to the public" and "is not directed at any product or industry." *Ibid.*

The Ninth Circuit's holding cannot be reconciled with the premises of a recent Third Circuit decision, *Michael* v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995). In *Michael*, the Third Circuit held that state common law requirements are subject to preemption under Section 360k, even though they govern numerous products in

addition to devices. In direct conflict with the principles underlying the Ninth Circuit's ruling, the Third Circuit held that "the statutory language of § 360k" preempts common law claims for breach of implied warranty "[d]espite the reference in 21 C.F.R. 808.1(d)(1) to laws of general applicability." 46 F.3d at 1323 n.4.[7] *Michael* followed an earlier Third Circuit case, *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540, 543 n.2 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994), which similarly held that 21 C.F.R. 808.1(d) does not exclude common law claims from preemption under section 360k.

The Ninth Circuit's holding also conflicts with the premises of similar decisions in product liability cases in the First, Second, Fifth, Seventh, Eighth and Eleventh Circuits. All of these courts have held that generally applicable state common law requirements are subject to preemption under the FDCA. *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995), cert. dismissed, 116 S. Ct. 1892 (1996); *Becker* v. *Optical Radiation Corp.*, 66 F.3d 18, 20 n.2, 20-21 (2d Cir. 1995); *Stamps* v. *Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.), cert. denied, 510 U.S. 824 (1993); *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), cert. denied, 505 U.S. 917 (1992); *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994); *Duncan* v. *Iolab Corp.*, 12 F.3d

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[7] The conflict in principle cannot be resolved by distinguishing the facts of *Michael*. Although the present case involves a state statute and *Michael* was a product liability case involving state common law requirements, this Court has indicated that FDCA preemption analysis does not depend on the source of state law. In *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), five Justices agreed that the FDCA preempts state requirements—regardless of whether they derive from common law doctrine or legislative enactment—if they are "different from, or in addition to," an applicable federal requirement. 116 S. Ct. at 2263 (opinion of O'Connor, J.); *id.* at 2259-60 (opinion of Breyer, J.).

194 (11th Cir. 1994). Because state common law requirements are neither established solely " 'with respect to' medical devices" nor "directed at any product or industry" (see Pet. App. 11a), these decisions directly conflict with the principles underlying the Ninth Circuit decision.

This conflict in principle is not likely to be resolved without action by this Court. The Ninth Circuit appears firmly committed to its errant view that the FDCA does not preempt state requirements applicable to medical devices as well as other products. The court below cited with favor the holding of an earlier Ninth Circuit case, *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), cert. denied, 116 S. Ct. 2579 (1996), which also preserved state requirements from preemption because they were not established solely with respect to medical devices. Pet. App. 8a-9a. In *Kennedy*, the Ninth Circuit denied preemption of common law claims, in part because it noted that "[s]ection 808.1(d)(1) provides that the MDA does not preempt laws of general applicability" and concluded that "[s]tate common law is a law of general applicability." 67 F.3d at 1459. The holding of the court below regarding state requirements therefore reaffirmed *Kennedy*, firmly entrenching the conflict with the other circuits on this issue.[8]

In addition, this Court's decision in *Lohr* did not resolve the conflict. On the one hand, the Court held that the FDCA regulatory scheme does not necessarily preclude " 'general' state requirements from ever being pre-empted." 116 S. Ct. at 2257. In particular, a majority of five Justices confirmed that generally applicable common law claims establish state "requirements" subject to possible preemption under section

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[8] In *Kennedy*, the Ninth Circuit recognized that its holding conflicted with the Third Circuit's decisions in *Michael* and *Gile*. See 67 F.3d at 1461 n.3.

360k(a). Justice O'Connor's opinion, which was joined by Chief Justice Rehnquist and Justices Scalia and Thomas, concluded that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." *Lohr*, 116 S. Ct. at 2262 (opinion of O'Connor, J.). Justice Breyer wrote a separate concurring opinion expressly agreeing with Justice O'Connor's discussion and conclusion on this point. *Id.* at 2259 (opinion of Breyer, J).[9]

On the other hand, the majority opinion authored by Justice Stevens denied preemption in part because the state common law requirements at issue were too general and "not specifically developed 'with respect to' medical devices." *Id.* at 2258. Justice Stevens' opinion concluded that "[t]hese state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices." *Ibid.*[10] The analytical approaches taken by the different *Lohr* opinions therefore failed to clarify the extent to which requirements that apply to products in addition to medical devices may be preempted.

Furthermore, this Court did not resolve the conflict through its disposition of other FDCA preemption cases that it held for decision on certiorari petitions pending the *Lohr* ruling. Five days after it decided *Lohr*, this Court denied the

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[9] Justices Stevens, Kennedy, Souter and Ginsburg expressly reserved the question whether common law duties are *never* "requirements" under the FDCA preemption provision. *Id.* at 2258-59 (opinion of Stevens, J.).

[10] Justice Breyer joined this portion of Justice Stevens' opinion, although he also concluded separately that he is "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.' " 116 S. Ct. at 2262.

petition for certiorari in *Kennedy* (thereby preserving the Ninth Circuit rule that the FDCA does not preempt requirements applicable to other products in addition to medical devices). 116 S. Ct. 2579. The denial of certiorari had the effect of continuing a conflict between Ninth Circuit doctrine and decisions of numerous other circuits.

In direct conflict with the Ninth Circuit, the First, Second, Eighth and Eleventh Circuits all decided prior to *Lohr* that generally applicable common law requirements *are* subject to preemption.[11] These circuits are unlikely to change course on their own. Because *Lohr* affirmed that common law claims are subject to preemption under appropriate circumstances, and because these cases all involved federal requirements that were not at issue in *Lohr*, they are still good law following *Lohr*. Indeed, the First Circuit has confirmed, following *Lohr*, that common law claims are subject to preemption under the FDCA. *Wilson* v. *Bradlees of New England, Inc.*, 96 F.3d 552, 554, 555-56 (1st Cir. 1996). In addition, because the Supreme Court has not considered any FDCA preemption cases in these circuits following *Lohr*, the conflict with the Ninth Circuit remains unresolved.

The same day that it denied the *Kennedy* petition, this Court vacated and remanded FDCA preemption cases from the Third, Fourth, Fifth, Sixth and Seventh Circuits, which before *Lohr* had affirmed preemption of generally applicable common law requirements in direct conflict with *Kennedy*.[12]

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[11] See, e.g., *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25; *Becker* v. *Optical Radiation Corp.*, 66 F.3d 18; *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167; *Duncan* v. *Iolab Corp.*, 12 F.3d 194.

[12] *English* v. *Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *vacated and remanded*, 116 S. Ct. 2575 (1996); *Duvall* v. *Bristol-Myers Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2575 (1996); *Bingham* v. *Mentor Corp.*, 89 F.3d 203 (5th Cir.), *vacated and*

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It is not likely that these circuits will change course on this issue, however, given the holding in *Lohr* that common law claims are subject to preemption. In three of these circuits (the Third, Fifth and Seventh), the decisions on remand will likely be influenced by older pre-*Lohr* decisions, discussed above, that affirm preemption of generally applicable common law requirements in conflict with Ninth Circuit doctrine.[13] In any event, regardless of how the Third, Fourth, Fifth, Sixth and Seventh Circuit cases are decided on remand, they will not resolve the substantial conflict between the Ninth and the First, Second, Eighth and Eleventh Circuits described above. As a result, only further action by this Court can clarify on a nationwide basis the extent to which the FDCA preempts requirements of general applicability.

B. The Conflict Regarding Preemptive Federal Requirements

Another fundamental premise of the Ninth Circuit's decision is its holding that federal requirements must apply exclusively to one type of medical device to preempt state law. The Ninth Circuit concluded that the district court was "wrong" when it held that Proposition 65 is preempted even though there are no " 'specific' [FDA] regulations relating to dental amalgam." Pet. App. 10a-11a. In so holding, the Court of Appeals rejected the district court's conclusion that the FDCA may preempt state law even if there is no

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remanded, 116 S. Ct. 2577 (1996); *Feldt* v. *Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2575 (1996); *Martin* v. *Telectronics Pacing Sys., Inc.*, 70 F.3d 39 (6th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1996); *Mitchell* v. *Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1996).

[13] *Michael* v. *Shiley, Inc.*, 46 F.3d 1316; *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540; *Stamps* v. *Collagen Corp.*, 984 F.2d 1416; *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330.

"requirement specifically applicable to one specific device." Pet. App. 12c.

The Ninth Circuit confirmed its analysis of federal requirements by reaffirming two of its prior decisions "narrowly construing the MDA's preemption clause." Pet. App. 8a-9a. One of these decisions is *Kennedy*, in which the court held that the FDA's PMA requirements are not sufficiently specific to be preemptive, because they apply to "*[a]ll* Class III devices" rather than to a single device type. 67 F.3d at 1459. The other decision is *Anguiano* v. *E.I. Dupont de Nemours & Co.*, 44 F.3d 806 (9th Cir. 1995), in which the court similarly premised preemption on the existence of a federal requirement "specifically addressing the device." 44 F.3d at 810.

The holding of the court below regarding preemptive federal requirements conflicts squarely with premises of decisions of four other circuits. The First, Third, Fifth and Eighth Circuits have held that the PMA requirements are preemptive "specific" requirements within the meaning of 21 C.F.R. 808.1(d), although they apply to hundreds of different device types. See *King* v. *Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), cert. denied, 510 U.S. 824 (1993); *Michael* v. *Shiley, Inc.*, 46 F.3d at 1324 (3d Cir.); *Stamps* v. *Collagen Corp.*, 984 F.2d at 1422 n.3, 1424 n.8 (5th Cir.); *Martello* v. *Ciba Vision Corp.*, 42 F.3d at 1169 (8th Cir.).[14] These decisions cannot be reconciled with the test applied by the court below, leaving the Ninth Circuit with a unique doctrine that drastically restricts preemption in comparison with the law of other circuits.

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[14] Almost 20 percent of the new Class III devices that enter the market each year are subject to the PMA requirements. Cf. H.R. Rep. No. 808, 101st Cong., 2d Sess. 14.

This Court's decision in *Lohr* did not resolve the conflict over the extent to which federal requirements applicable to numerous devices may be preemptive under section 360k(a). In *Lohr*, the Court did not articulate a clear-cut test for the lower courts to identify a preemptive federal requirement. On the one hand, the Court stated that it did "not believe" that the MDA preemption provision and the FDA's preemption regulation "necessarily preclude[] 'general' federal requirements from ever pre-empting state requirements." 116 S. Ct. at 2257. On the other hand, the Court held that the federal manufacturing and labeling requirements at issue in *Lohr* were too general to preempt the particular common law claims under review. *Id.* at 2257-58.[15] The Court's primary guidance for the lower courts was to state that there must be "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement" to address the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Ibid.* By adopting a case-by-case approach, *Lohr* did little to resolve the fundamental conflict in principle between the circuits regarding the test for preemptive federal requirements.

Furthermore, the circuits do not appear likely to resolve the conflict on their own. Given its reaffirmation of prior circuit doctrine, the Ninth Circuit is unlikely to reconsider its test for preemptive federal requirements. Similarly, the First and Eighth Circuits have no reason to reconsider their conflicting test, in light of the fact that *Lohr* does not exclude

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[15] The Court did *not* hold that these federal requirements can *never* preempt state law. See *ibid.* Indeed, should this Court grant this petition, petitioners will argue, inter alia, that in the particular context of this case (including the FDA's decision not to adopt reproductive toxicity warnings for dental mercury) the federal labeling requirements at issue in *Lohr* do preempt Proposition 65.

general federal requirements from the scope of the preemption provision. See 116 S. Ct. at 2257. Furthermore, the Third and Fifth Circuits, which are considering cases remanded in the wake of *Lohr*, see pp. 17-18 & n.12, *supra*, may add fuel to—but cannot resolve—the conflict among these other circuits.

C. This Court Should Resolve the Conflict Regarding Preemption Standards

This Court should resolve the conflict among the circuits regarding the tests for state and federal requirements encompassed by the FDCA preemption provision. Currently, state legislative power over medical devices varies greatly from State to State. In the Ninth Circuit, the scope of preemption under the FDCA is extremely narrow, giving legislatures in Ninth Circuit states extensive authority to regulate medical devices. The FDA almost never regulates with requirements specific enough to meet the Ninth Circuit's test for preemptive federal requirements; there are fewer than two dozen substantive device-specific FDA regulations, and only one device-specific requirement in the FDCA. It also is unusual for States to enact consumer protection statutes that regulate medical devices but no other products, rendering the Ninth Circuit's test for state requirements extraordinarily difficult to satisfy. The Ninth Circuit's limitations on FDCA preemption therefore authorize expansive state legislative power. In contrast, legislative authority is much more limited in the States of other circuits that interpret the FDCA preemption provision more broadly.

As a result of conflicting preemption standards among the circuits, national medical device manufacturers doing business in all fifty States currently confront a confusing and disjointed pattern of regulatory requirements. The warning requirements imposed under Proposition 65 provide an apt illustration. Manufacturers that distribute dental mercury on a nationwide basis are subject to burdensome warning re-

quirements in California. One recent "bounty hunter" case brought by respondent ELF was resolved through a consent judgment that required the defendant to pay $328,000 in civil penalties and withdraw the device from commerce in California if its dentist customers failed to post warning signs in their offices encouraging patients to inquire about alternative dental restoration materials. *Environmental Law Found.* v. *Jeneric/Pentron Inc.*, No. 957039 (Cal. Super. Ct. San Francisco County Dec. 13, 1993) (stipulation for judgment). In contrast, other states in the Ninth Circuit are free to require different warnings while states outside the Ninth Circuit remain governed by federal warning requirements.

These differing requirements disrupt the rational and efficient development, production, and sale of critical medical devices, undermining the very purpose of the FDCA preemption provision. Congress enacted that provision to enhance uniformity of regulatory requirements so that the regulatory structure would not stifle technological innovations of vital importance to the public health. Until this Court resolves the disarray among the circuits regarding preemption standards, this burden on innovation will persist. This Court should grant this petition to establish a uniform rule of law necessary for an efficient and rational medical device regulatory system.

II. THIS CASE PRESENTS AN IMPORTANT FEDERAL QUESTION THAT HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THIS COURT

A decision by this Court on the question presented would resolve a significant question of federalism profoundly important to the public health—whether the FDCA places regulation of medical devices in the hands of an expert federal agency or gives state legislatures relatively free reign to dictate regulatory requirements. This Court never has considered the scope of state legislative power over medical de-

vices. A decision in this case would allow this Court to resolve the tension between federal control of medical devices and control by the States, which "traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Metropolitan Life Ins. Co.* v. *Massachusetts*, 471 U.S. 742, 756 (1985) (internal quotation marks omitted).

In particular, a decision by this Court in this case would resolve the significant question whether a state legislature may impose requirements on medical devices that FDA experts have considered and affirmatively rejected as unfounded. Although this Court has explained in other contexts that intentional inaction by a federal regulator under a comprehensive regulatory scheme may preempt conflicting state law, see, e.g., *Puerto Rico Dep't of Consumer Affairs* v. *Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988), it never has addressed the issue under the FDCA. By granting the petition, the Court would help define the FDA's authority to specify what is—and just as importantly, what is not—required to ensure that the public health is protected.

The FDA has long recognized that under some circumstances, inappropriate product warnings may have an adverse effect on the public health. Unfounded warnings may cause patients to discontinue valuable therapies, shift to new therapies that present greater risks, or suffer unnecessary psychological trauma. The FDCA itself expresses the importance of these concerns about inappropriate warnings, granting the FDA discretion, based on its scientific expertise, to determine whether patients should be notified of particular risks arising from medical devices, or whether "notice to such individuals would present a *greater danger* to the health of such individuals than no such notification." 21 U.S.C. 360h(a) (emphasis added).

The warning requirements that gave rise to the present case illustrate well the importance of defining the FDA's

authority to regulate through intentional inaction. According to a recent government report, one of the particular concerns raised by dental mercury warnings is the prospect that thousands of patients might respond by having existing dental fillings removed and replaced by potentially riskier and more expensive devices, at an increased cost that could exceed $12 billion per year. Public Health Service, Department of Health and Human Services, *Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation* xi, 10, 17 (1993). By granting the petition, the Court would have the opportunity to define the FDA's authority to maintain control over its critical regulatory program by barring States from imposing unwarranted warning requirements.

At the same time, granting the petition would allow the Court to clarify the circumstances under which the absence of federal regulation *does* allow the States room to regulate medical devices. The Ninth Circuit noted that if the FDA's inaction on a particular subject were always sufficient to trigger preemption, manufacturers would be free to ignore state consumer protection laws during the period that the FDA is considering whether to take regulatory action. See Pet. App. 13a. If the Court grants review in this case, it could define the circumstances under which state laws can protect users of medical devices in the absence of federal regulation.

A decision in this case also could define more generally the relationship between state and federal power over the critically important medical device industry. This case provides the Court with an excellent opportunity to address this important issue of federalism, because the federal and state interests at issue are both significant; the federal statute derives from a substantial congressional concern for strong regulation of medical devices at the federal level, and the state statute arises from traditional core state concerns regarding consumer protection.

In addition, this case presents a superb opportunity to clarify the balance of power between the state and federal governments, because the particular assertion of state legislative power under Proposition 65 is extraordinary. At a minimum, Proposition 65 allows the State of California to *penalize* manufacturers and distributors for marketing a device without Proposition 65 warnings, even though federal law *authorizes* marketing the same device without such warnings. See Cal. Health & Safety Code § 25249.7(b) (penalties of $2,500 per day for each violation of Proposition 65 warning requirements). In addition, Proposition 65 allows imposition of these state penalties for federally-authorized conduct through "bounty hunter" suits by private parties, *even if the State of California declines suit. Id.* § 25249.7(d). Indeed, the current case arises in the context of a decision by the State of California not to bring suit under Proposition 65 regarding dental mercury, because it had "completed an extensive review of the literature" and determined that "there is no conclusive evidence of the reproductive toxicity of mercury." Letter from Chief Deputy Attorney General to Kerr Manufacturing Co. of Sept. 20, 1993 (C.A. Supplemental Excerpts of Record at SER 952).[16] The unusually expansive state power asserted under Proposition 65 gives the Court an

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[16] Although compelled to defend Proposition 65 in this suit, the California Attorney General would be the first to admit that Proposition 65 suits have a confounding effect on federal and state laws. In early 1996, the Attorney General sponsored a bill in the California Assembly to control suits by "bounty hunters." The bill's preamble states that actions by "irresponsible private groups" imposing warning requirements under this law have "resulted in an inaccurate perception of the requirements of the act and have resulted in businesses providing warnings * * * so as to prevent being subjected to unfounded litigation, thereby generating needless warnings that confuse the public and reduce the effectiveness of necessary warnings." A. 3160, 1995-96 Regular Sess. (Cal. introduced Feb. 23, 1996).

unusually good context for addressing the important federalism issues at stake.[17]

Finally, this case is appropriate for Supreme Court review, because Proposition 65 may *require* warnings that *violate* federal law. A recent report of the Department of Health and Human Services concluded that federal law prohibits certain warnings currently being imposed under Proposition 65:

> Advertising is considered to be labeling. If individual dentists were participating in *false advertising such as claiming that dental amalgams are toxic to humans* or causative agents for diseases, and if literature purporting [sic] these claims were on the premises of the dentist's office, *FDA would have the authority to take legal action* against that dentist.

Dental Amalgam: A Scientific Review at VI-5 (emphasis added).[18] The stark contrast between state and federal requirements in this case presents the best opportunity this Court has yet had to define the complex relationship between federal and state regulatory power over critically important medical devices.

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[17] The national significance of the federalism issues posed by Proposition 65 is confirmed by a recent *Federal Register* notice. The Occupational Safety and Health Administration presently is considering whether to preempt the application of Proposition 65 and its "bounty hunter" provisions to products distributed for use in work places. See 61 Fed. Reg. 48,443 (Sept. 13, 1996).

[18] Respondent ELF has demanded and obtained such warnings under the authority of Proposition 65 and is currently threatening new litigation against petitioners on the same issue. See p. 22, *supra*.

CONCLUSION

This Court should grant the petition for certiorari.

Respectfully submitted,

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